AMENDMENTS TO THE CLAIMS

1. (Original) A method for reducing hyperglycemia and stabilizing the level of serum glucose comprising administering to an individual in need thereof between about 50 and 1,000 micrograms per day of chromium as synthetic chromic tripicolinate in combination with between about 25 μg and 200 mg per day of biotin, wherein the amounts of chromic tripicolinate and biotin are selected together to provide a greater than additive effect.

2. (Original) The method of claim 1, comprising administering between about 500 and 1,000 micrograms per day of chromium as synthetic chromic tripicolinate.

3. (Original) The method of claim 1, comprising administering between about 1 mg and 100 mg biotin per day.

4. (Original) The method of claim 1, wherein said chromic tripicolinate is in a pharmaceutically acceptable carrier.

5. (Original) The method of claim 1, wherein said biotin is in a pharmaceutically acceptable carrier.

6. (Original) The method of claim 1, wherein said chromic tripicolinate is orally administered.

7. (Original) The method of claim 1, wherein said biotin is orally administered.

8. (Original) The method of claim 1, wherein said chromic tripicolinate is parenterally administered.

9. (Original) The method of claim 1, wherein said biotin is parenterally administered.

10. (Original) A pharmaceutical composition comprising chromium as synthetic chromic tripicolinate and biotin, wherein the ratio of chromium to biotin is between about 2:1 and 1:200 (w/w), wherein the amounts of chromic tripicolinate and biotin are selected together to provide a greater than additive effect.

11. (Currently Amended) A method for reducing hyperglycemia ~~or stabilizing the level of serum glucose~~ comprising administering to an individual in need thereof between about 50 and 1,000 micrograms per day of chromium as synthetic chromic tripicolinate in combination with between about 25 μg and 200 mg per day of biotin, wherein the amounts of chromic tripicolinate and biotin are selected together to provide a ~~greater than additive~~ synergistic effect in reducing blood glucose levels.

12. (Currently Amended) A method for reducing hyperglycemia ~~or stabilizing the level of serum glucose~~ comprising administering to an individual in need thereof a composition consisting essentially of between about 50 and 1,000 micrograms per day of chromium as synthetic chromic tripicolinate in combination with between about 25 micrograms and 200 milligrams per day of biotin, wherein the amounts of chromic tripicolinate and biotin are selected together to provide a ~~greater than additive~~ synergistic effect in reducing blood glucose levels.

13. (Previously Presented) The method of claim 12, wherein the individual is a human.

14. (Previously Presented) The method of claim 12, comprising administering between about 500 and 1,000 micrograms per day of chromium as synthetic chromic tripicolinate.

15. (Previously Presented) The method of claim 12, comprising administering between about 1 milligram and 100 milligrams biotin per day.

16. (Currently Amended) The method of claim 12, comprising administering about 600 micrograms of chromium as synthetic chromic tripicolinate and about 300 micrograms of biotin, wherein the amounts of chromic tripicolinate and biotin are selected together to provide a ~~greater than additive~~ synergistic effect in reducing blood glucose levels.

17. (Currently Amended) The method of claim 12, comprising administering about 400 micrograms of chromium as synthetic chromic tripicolinate and about 200 micrograms of biotin, wherein the amounts of chromic tripicolinate and biotin are selected together to provide a ~~greater than additive~~ synergistic effect in reducing blood glucose levels.

18. (Previously Presented) The method of claim 12, wherein said chromic tripicolinate is in a pharmaceutically acceptable carrier.

19. (Previously Presented) The method of claim 12, wherein said biotin is in a pharmaceutically acceptable carrier.

20. (Previously Presented) The method of claim 12, wherein said chromic tripicolinate is orally administered.

21. (Previously Presented) The method of claim 12, wherein said biotin is orally administered.

22. (Previously Presented) The method of claim 12, wherein said chromic tripicolinate is parenterally administered.

23. (Previously Presented) The method of claim 12, wherein said biotin is parenterally administered.

24. (Currently Amended) A pharmaceutical composition consisting essentially of chromium as synthetic chromic tripicolinate and biotin, wherein the ratio of chromium to biotin is between about 2:1 and 1:200 (w/w), wherein the amounts of chromic tripicolinate and biotin are selected together to provide a ~~greater than additive~~ synergistic effect in reducing blood glucose levels.

25. (Currently Amended) A pharmaceutical composition comprising about 600 micrograms/day of chromium as synthetic chromic tripicolinate and about 300 micrograms/day of biotin, wherein the amounts of chromic tripicolinate and biotin are selected together to provide a ~~greater than additive~~ synergistic effect in reducing blood glucose levels.

26. (Currently Amended) A pharmaceutical composition consisting essentially of about 600 micrograms/day of chromium as synthetic chromic tripicolinate and about 300 micrograms/day of biotin, wherein the amounts of chromic tripicolinate and biotin are selected together to provide a ~~greater than additive~~ synergistic effect in reducing blood glucose levels.

SUMMARY OF INTERVIEW

On February 28, 2005, James Komorowski (Vice President of Technical Services and Scientific Affairs for Assignee), and the undersigned, Ned Israelsen (Attorney for Applicant) met with Examiner Cook regarding the instant Application. The undersigned would like to thank Examiner Cook for the courtesy extended during that interview, and the helpful nature of the Examiner's suggestions. The Examiner Interview Summary Record prepared by the Examiner at the interview accurately reflects the discussion, and the substance of the interview is further summarized below.

The Applicant proposed amending Claims 11 and 12 to delete the phrase "or stabilizing the level of serum glucose." Mr. Israelsen noted that support for the amendment could be found in the portion of the specification that discusses administering chromium tripicolinate and biotin in order to reduce important risk factors associated with Type II diabetes. Examiner Cook agreed to the amendment provided that Applicants submit objective evidence that establishes that the major focus of therapy to treat Type II diabetes is reduction of hyperglycemia.

The rejection of the claims as being obvious under 35 U.S.C. § 103(a) over Anderson et al. and Maebashi et al. was also discussed. Applicant's showed data reflecting synergistic effects when chromium tripicolinate and biotin were administered to muscle cells *in vitro*. Examiner Cook agreed those data should overcome the rejection under 35 U.S.C. § 103(a) provided that Applicants submit a declaration presenting those data to show that the combination of chromium tripicolinate and biotin showed unexpected results regarding glucose metabolism relative to each agent alone.

Examiner Cook asked that the claims be amended to more fully explain what is meant by "greater than additive effect." The undersigned agreed to make such an amendment to the new claims, but stated that the issue would be argued instead with respect to the original claims to avoid amendments to original claims.